REMARKS

Claims 1-9, 11 and 13-25 are currently pending in this application. Claims 10, 12, 21 and 22 has been canceled. Claims 1-4, 7, 8, 11, 13, 16, 17, 20, 23 and 25 have been amended. Applicant has carefully reviewed the Office Action and respectfully request reconsideration of the claims in view of the remarks presented below.

Election/Restrictions

Restriction to one of the following inventions was indicated as required:

I. Claims 1-20 and 23-25, drawn to a system and method for controlling the recording of diagnostic data within an implantable device.

II. Claims 21 drawn to a method of for controlling the recording of diagnostic data within an implantable medical device.

III. Claims 22 drawn to a method for controlling the recording of diagnostic data within an implantable device.

Based on a telephonic provisional election, claims 21 and 22 were withdrawn from further consideration as being drawn to a non-elected invention. Applicants affirm their provisional invention and accordingly have canceled claims 21 and 22.

Specification Objections

Paragraph [0001] was objected to for not including the serial number of the referenced patent application. Paragraph [0001] has been amended to include the appropriate serial number.

Claim Objections

Claim 18 was objected to as being unclear due to grammatical mistakes. Applicant believes claim 18 is grammatically correct and clear. If the Examiner maintains this objection, clarification is requested in the next communication from the Office.

Claim Rejections Under 35 U.S.C. §102

Claims 1-3, 12, 19-20 and 23-25 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Publication 2002/0147409 (Baker).

Independent claims 1, 23 and 25 relate to methods and systems that conserve implantable medical device power by recording diagnostic data under conditions that provide for the recording of possible impending arrhythmia data without requiring the continuous recording of data. For example, Claim 1 recites a method for controlling the recording of diagnostic data within an implantable medical device, the method comprising monitoring cardiac rhythm through the implantable medical device; evaluating the cardiac rhythm to determine the likelihood that a cardiac arrhythmia will arise; and controlling the recording of diagnostic data such that no diagnostic data is recorded until it has been determined that a cardiac arrhythmia is likely to arise. Claims 23 and 25 recite systems generally corresponding to the features of claim 1

Baker discloses an external apparatus for monitoring atrial fibrillation. See Abstract. Baker does not disclose an implantable medical device. Upon placement of hands on electrodes, a microcontroller starts a timer. See paragraph [0034], lines 1-2. Following starting of the timer, data is progressively acquired through the electrodes and stored in memory. See paragraph [0035]. Thus, recording begins automatically when the patient's hands touch the electrodes, regardless of whether atrial fibrillation is either present or likely to occur.

Applicant submits that Baker fails to disclose the combinations of elements and features recited in independent claims 1, 23 and 25, including at least the monitoring of cardiac rhythm through the implantable medical device, the evaluating of cardiac rhythm to determine the likelihood that a cardiac arrhythmia will arise and the recording of diagnostic data such that no diagnostic data is recorded until it has been determined that a cardiac arrhythmia is likely to arise. Accordingly, Applicant requests reconsideration of the §102 rejections of claims 1, 23 and 25.

Applicants further submit that, by virtue of the incorporation of subject matter recited in their respective independent base claim, each of dependent claims 2, 3, 19, 20 and 24 is also novel over Baker. Aside from the foregoing basis of novelty, Applicant believes that dependent claims recite additional novel subject matter. For example, regarding claim 2, Baker does not disclose any identification of periods of time wherein there is an elevated risk of an arrhythmia. Baker simply records data and then determines if atrial fibrillation is present. Baker also does not record data only during periods of time wherein there is an elevated risk of an arrhythmia.

Regarding claim 3, low or reduced heart rate variability is associated with ventricular arrhythmias whereas high heart rate variability is associated with atrial arrhythmias. See paragraph [0056] of Applicant's specification. Accordingly, Baker – which addresses an atrial arrhythmia, i.e., atrial fibrillation – does not disclose identifying periods of elevated risk of arrhythmia corresponding to periods of time of reduced heart rate variability.

Regarding claim 20, Bakers records data whether or not atrial fibrillation is present or likely to arise. Accordingly, it does not disclose recording diagnostic data in a temporary memory only if a cardiac arrhythmia is likely to arise.

Claims 1, 2, 4 and 12 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,275,734 (McClure).

Independent claim 1 recites a method for controlling the recording of diagnostic data within an implantable medical device, the method comprising monitoring cardiac rhythm through the implantable medical device; evaluating the cardiac rhythm to determine the likelihood that a cardiac arrhythmia will arise; and controlling the recording of diagnostic data such that no diagnostic data is recorded until it has been determined that a cardiac arrhythmia is likely to arise.

McClure discloses a system that records cardiac rhythm data in memory only upon a determination that the heart is already experiencing abnormal heart activity. See column 8, lines 26-30. McClure does not teach or suggest recording diagnostic

data after it has been determined that a cardiac arrhythmia is likely to arise. Instead, McClure waits until a cardiac arrhythmia is present before it starts recording.

Applicant submits that McClure fails to disclose the combinations of elements and features recited in independent claim 1, including at least the evaluating of cardiac rhythm to determine the likelihood that a cardiac arrhythmia will arise and controlling the recording of diagnostic data such that no diagnostic data is recorded until it has been determined that a cardiac arrhythmia is likely to arise. Accordingly, Applicant requests reconsideration of the §102 rejections of claim 1.

Applicants further submit that, by virtue of the incorporation of subject matter recited in their respective independent base claim, each of dependent claims 2 and 4 is also novel over McClure. Aside from the foregoing basis of novelty, Applicant believes that dependent claims recite additional novel subject matter. For example, regarding claim 2, McClure does not disclose any identification of periods of time wherein there is an elevated risk of an arrhythmia.

Claims 1, 2 and 8-13, 15 and 18 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,908,392 (Wilson).

Independent claim 1 recites a method for controlling the recording of diagnostic data within an implantable medical device, the method comprising monitoring cardiac rhythm through the implantable medical device; evaluating the cardiac rhythm to determine the likelihood that a cardiac arrhythmia will arise; and controlling the recording of diagnostic data such that no diagnostic data is recorded until it has been determined that a cardiac arrhythmia is likely to arise.

Wilson discloses a system that continuously records data into temporary buffers without reference to any type of criteria. See column 8, lines 49-54. Upon meeting a particular criteria, data from the temporary buffers is transferred to a snap-shot buffer for long-term storage. See column 10, lines 16-25 and lines 41-44. Thus the Wilson system continuously records data.

Applicant submits that Wilson fails to disclose the combinations of elements and features recited in independent claim 1, including at least the controlling of the recording of diagnostic data such that no diagnostic data is recorded until it has been determined that a cardiac arrhythmia is likely to arise. Accordingly, Applicant requests reconsideration of the §102 rejections of claim 1.

Applicant further submits that, by virtue of the incorporation of subject matter recited in their respective independent base claim, each of dependent claims 2 and 8-13 is also novel over Wilson. Aside from the foregoing basis of novelty, Applicant believes that dependent claims recite additional novel subject matter. For example, regarding claim 2, Wilson does not record data only during periods of time wherein there is an elevated risk of an arrhythmia. Regarding claim 8, Wilson does not activate recording only prior to a predicted onset of arrhythmia.

Claim Rejections Under 35 U.S.C. §103

Claim 5 was rejected under 35 U.S.C. §103(a) as being unpatentable over McClure in view of U.S. Patent No. 6,400,982 (Sweeney). Claims 6 and 7 were rejected under 35 U.S.C. §103(a) as being unpatentable over McClure in view of Sweeney and further in view of Wilson. Claim 14-18 were rejected under 35 U.S.C. §103(a) as being obvious over Wilson.

In view of the foregoing analysis of independent claim 1 in view of each of Baker, McClure and Wilson, Applicant believes that the rejections under §103 are moot as dependent claims 5-7 and 14-18 depend from allowable independent base claims.

Furthermore, regarding claims 5-7, Sweeney was cited for disclosing arrhythmia risk period identification. In view of this, it was concluded that it would have been obvious to one of ordinary skill in the art to modify McClure's diagnostic data recorder with Sweeney's risk period identification. Without addressing the substance of the Sweeney disclosure, it is noted that claim 5 is not concerned with risk period identification. In fact, claim 5 addresses the scenario where ventricular tachycardia has already been detected and how data recording is controlled in response to such

detection. Claims 6 and 7 recite further features of controlling data recording under claim 5. Accordingly, Applicant submits that the rational behind the obviousness rejections of claim 5-7 based on McClure and Sweeney presented in the Office Action is without reason and should be either withdrawn or more clearly articulated.

CONCLUSION

Applicants have made an earnest and bona fide effort to clarify the issues before the Examiner and to place this case in condition for allowance. Therefore, allowance of Applicant's claims 1-9, 11 and 13-25 is believed to be in order.

Respectfully submitted,

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Date

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